

PFAS Unveiled: Understanding Regulatory Dynamics in Food Packaging

September 14 | 10 AM MST

Meet

Your Moderator



Ashley Minso
Digital Marketing Manager

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Group Leader | knoell



Kari Barnes

Regulatory Standards Manager | TraceGains

Meet

Your Speakers

PFAS restrictions in relation with Food Contact Materials (FCM) – recent regulatory developments

14 September 2023

Dr Ioan Paraschiv

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FOOD & FOOD CONTACT MATERIALS



MEDICAL DEVICES

- **Regulatory Compliance Reviews for Food Contact Materials (FCM) & Final articles**

- Globally (US, EU, China, Japan, LATAM, Korea, UK, etc.);
- Determine compliance status and next steps to achieve compliance;
- Advise and coordinate analytical testing (EU OML/SML, 21 CFR);
- Preparation of DoCs (Declaration of Compliance).

- **Preparation and Submission of Food Contact Notifications**

- Globally (US FCN, EU EFSA, China Petition, etc.);
- Requires regulatory expertise, toxicology support, and migration testing;
- Liaise with and provide responses to questions from Government Authorities (or “CA” Competent Authorities).

- **Preparation and Submission of dossiers for food ingredients**

- New Dietary Ingredient notifications;
- Novel Food Dossiers / Applications;
- GRAS Notifications.

- **Food and FCM - Toxicology Support**

- Conduct risk assessments to determine safe use of FCMs;

- **Strategic and Regulatory Consulting**

- On-demand regulatory and toxicology support;
- Supply Chain management support (ensure compliance along supply chain from raw material manufacturers to final article manufacturers);
- Educational support via Workshops and Seminars.



- ▶ What is PFAS?
- ▶ Uses of PFAS in food industry
- ▶ PFAS regulations in US
- ▶ PFAS in EU
- ▶ Next Steps

► Perfluoroalkyl and Polyfluoroalkyl Substances (PFAS)

► US State Regulations (from Toxics in Packaging Clearinghouse model legislation) definition on PFAS:

- *all members of the class of fluorinated organic chemicals containing at least one fully fluorinated carbon atom*
- this is the most commonly used definition by US States' legislations on PFAS

► US EPA definition on PFAS:

- *per- and polyfluorinated substances that structurally contain the unit $R-(CF_2)-C(F)(R')R''$; both the CF_2 and CF moieties are saturated carbons and none of the R groups (R , R' or R'') can be hydrogen*
- Current proposed US EPA definition change was released on 22 June 2023:
- *(i) $R-(CF_2)-CF(R')R''$, where both the CF_2 and CF moieties are saturated carbons*
- *(ii) $R-CF_2OCF_2-R'$, where R and R' can either be F , O , or saturated carbons **or***
- *(iii) $CF_3C(CF_3)R'R''$, where R' and R'' can either be F or saturated carbons*

► EU definition on PFAS: (may be revised in the future)

- *any substance that contains at least one fully fluorinated methyl (CF_3-) or methylene ($-CF_2-$) carbon atom (without any $H/Cl/Br/I$ attached to it)*

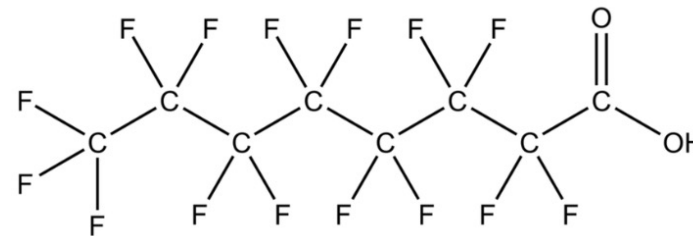
► UK definition on PFAS:

- *substances must contain at least one fully fluorinated methyl carbon atom, or two or more contiguous perfluorinated methylene groups*

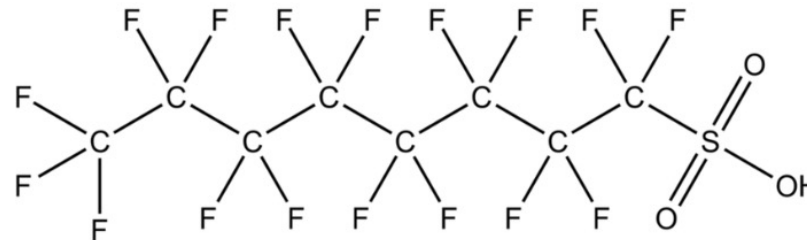
What are PFAS ?

- Most known PFAS and how all started:

- Perfluorooctanoic acid (PFOA)
 - (CAS RN 335-67-1)



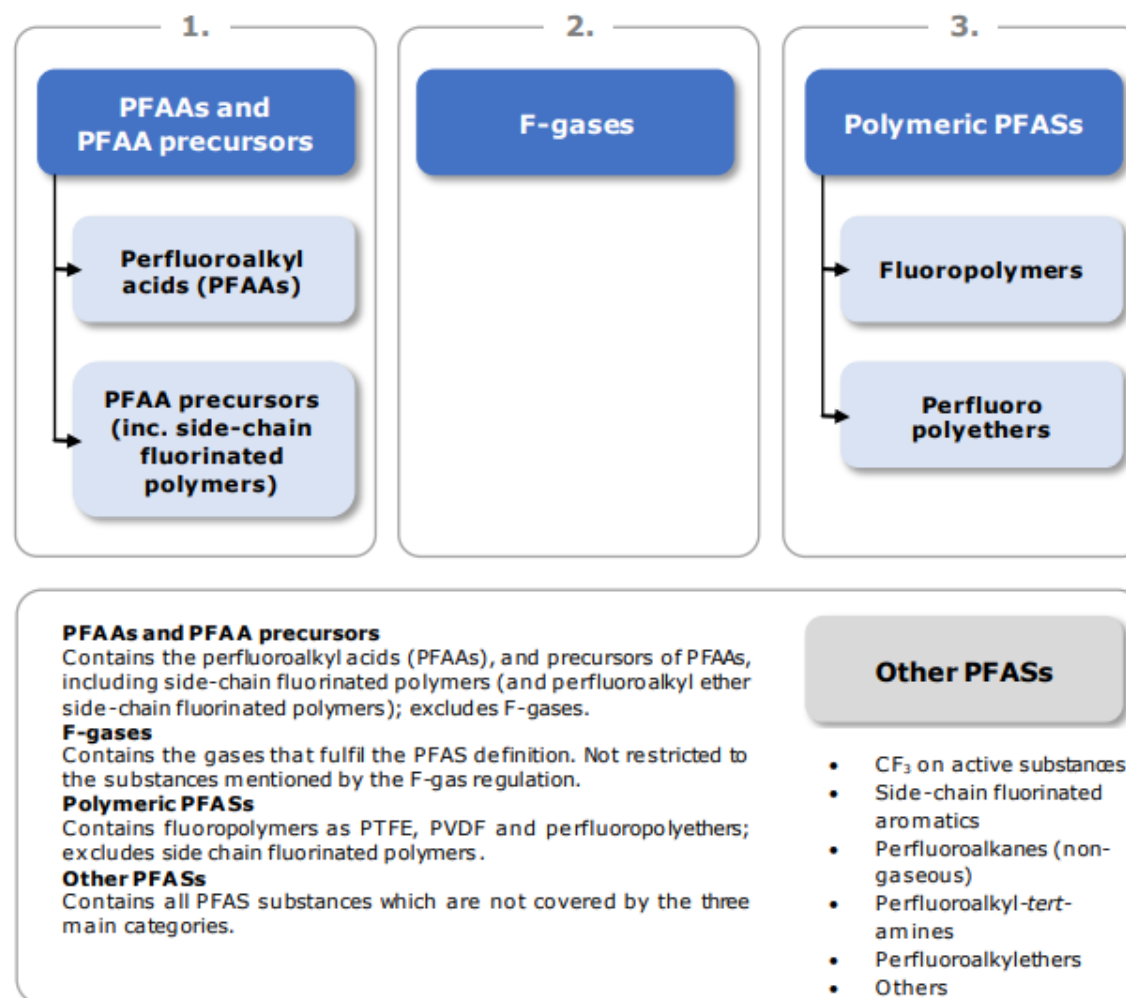
- Perfluorooctane sulfonic acid (PFOS)
 - (CAS RN 1763-23-1)



- One database example on PFAS:

<https://comptox.epa.gov/dashboard/chemical-lists/PFASSTRUCT>

A more complete picture on PFAS*



* ECHA, Annex XV Restriction Report, 22 March 2023: <https://echa.europa.eu/documents/10162/f71f3bed-e48d-5004-d195-e293c38d0602>

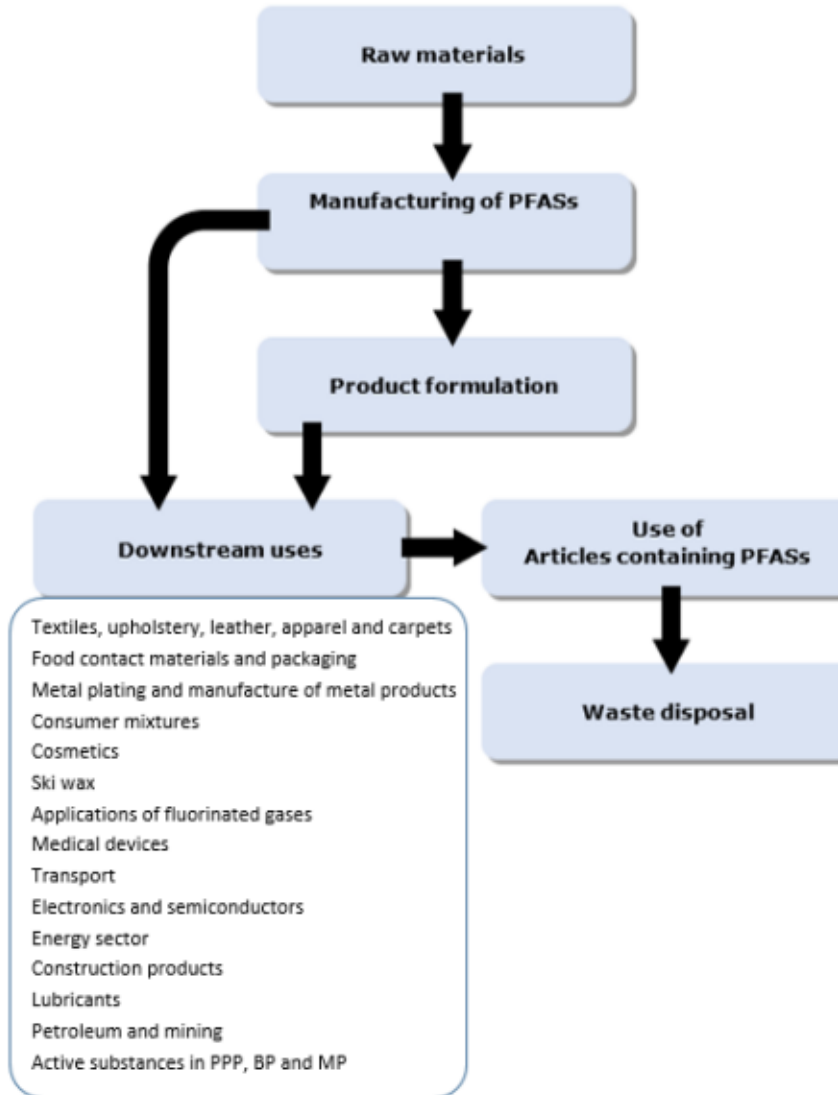
Uses of PFAS in food industry

- ▶ PFAS that are authorized for use in contact with food generally fall into four application categories:
 - ▶ **Non-stick cookware:** PFAS may be used as a coating to make cookware non-stick
 - ▶ **Gaskets, O-Rings, and other parts used in food processing equipment:** PFAS may be used as a resin in forming certain parts used in food processing equipment that require chemical and physical durability
 - ▶ **Processing aids:** PFAS may be used as processing aids for manufacturing other food contact polymers to reduce build-up on manufacturing equipment
 - ▶ **Paper/paperboard food packaging:** PFAS may be used as grease-proofing agents in fast-food wrappers, microwave popcorn bags and take-out paperboard containers to prevent oil and grease from foods from leaking through the packaging



<https://www.fda.gov/food/process-contaminants-food/authorized-uses-pfas-food-contact-applications#:~:text=Paper%2Fpaperboard%20food%20packaging%3A%20PFAS,from%20leaking%20through%20the%20packaging.>

PFAS in supply chain including Food Contact Materials (FCM)*



* ECHA, Annex XV Restriction Report, 22 March 2023:
<https://echa.europa.eu/documents/10162/f71f3bed-e48d-5004-d195-e293c38d0602>

- Consider unintentional uses and possibility of cross-contamination:
 - Recycled materials
 - **Fluorination** process for HDPE
 - US EPA did a study to test the leaching potential of PFAS in different brands of HDPE fluorinated containers
 - The results from this study released in 2022 indicated that liquid products packaged in HDPE containers treated with fluorination technology could leach certain PFAS into products from the container walls
 - Environmental contamination
 - PFAS used frequently in textiles, automotive, firefighting foams leaching into groundwater
 - Various states are also passing specific restrictions on these uses as well

<https://www.epa.gov/pesticides/epa-releases-data-leaching-pfas-fluorinated-packaging>



- ▶ Currently, there are no US Federal level regulations banning PFAS from use in Consumer Products or packaging
 - ▶ There has been action by US EPA to restrict PFAS uses
 - ▶ Toxic Substances Control Act (TSCA) PFAS Reporting Rule set to publish September 2023
 - Who must report:
 - *“Persons who have manufactured a chemical substance identified in § 705.5 at any period from **January 1, 2011** to the effective date of this rule.”*
 - This includes importers who used PFAS for food contact articles
- ▶ More than 20 US States have enacted laws targeting PFAS; these regulations set drinking water concentration limits and restricting the use of PFAS in many consumer products including packaging, textiles, and cosmetics
 - ▶ States’ regulations may be “preempted” by US Federal regulation in the same category if Federal laws are enacted

- in 2020, in response to the US FDA's post-market scientific review, manufacturers agreed to a 3-year market phase-out of food contact substances containing short-chain PFAS with 6:2 fluorotelomer alcohol (6:2 FTOH), and to cease all sales of these substances in the U.S. market by December 31, 2023
 - This was a **voluntary** phase out
 - US Food Contact notifications (FCN) database

646	Introduction into interstate commerce and delivery for introduction into interstate commerce voluntarily ceased by the manufacturer Copolymers of 2-perfluoroalkylethyl acrylate, 2-N,N-diethylaminoethyl methacrylate, glycidyl methacrylate, acrylic acid, and methacrylic acid (CAS Reg. No. 870465-08-0).	DuPont Chemical Solutions Enterprise	Sep 30, 2006
628	Introduction into interstate commerce and delivery for introduction into interstate commerce voluntarily ceased by the manufacturer Copolymer of 2-perfluoroalkylethyl acrylate, 2-(dimethylamino)ethyl methacrylate, and oxidized 2-(dimethylamino)ethyl methacrylate (CAS Reg. No. 479029-28-2).	Clariant Corporation	Oct 10, 2006
604	Introduction into interstate commerce and delivery for introduction into interstate commerce will be voluntarily ceased by the manufacturer Copolymer of perfluorohexylethyl methacrylate, 2-N,N-diethylaminoethyl methacrylate, 2-hydroxyethyl methacrylate, and 2,2'-ethylenedioxydiethyl dimethacrylate, acetic acid salt (CAS Reg. No. 863408-20-2) or malic acid salt (CAS Reg. No. 1225273-44-8).	Asahi Glass Company, Ltd. (Manufacturer) AGC Chemicals Americas, Incorporated	Aug 5, 2006

https://www.cfsanappsexternal.fda.gov/scripts/fdcc/?set=FCN&sort=FCN_No&order=DESC&startrow=1&type=basic&search=perfluoro



PFAS in (food) packaging – US States legislative measures



State	Effective date	Type of packaging?	Additional Note	Intentional Use?
California	After January 1, 2023	Paper, not required to have direct food contact	Bans intentionally added PFAS as well as unintentionally added PFAS above 100 ppm	No
Colorado	After January 1, 2024	Paper, direct food contact	Additional restrictions and labeling requirements for PFAS in other categories including cookware	Yes
Connecticut	After December 31, 2023	Any, direct food contact	Manufacturer or distributor can rely on a Certificate of Compliance (CoC) from their supplier	Yes
Hawaii	After December 31, 2024	Paper, specific identified products	Safer alternative provision	Yes
Maine	Not able to be promulgated until safer alternative identified by legislature.	Any, specific identified commodities	Safer alternative provision	Yes
Maryland	After January 1, 2024	Paper, direct food contact	Manufacturers must provide a CoC upon request	Yes



PFAS in (food) packaging - US States legislative measures

State	Effective date	Type of packaging?	Additional Note	Intentional use?
Minnesota	After January 1, 2024	Any, food contact not required	Another bill currently set to pass that would ban all non-essential uses of PFAS in products by 2030 in Minnesota	Yes
New York	After December 31, 2022	Paper, direct food contact	Retailers are required to collect CoCs from their manufacturers	Yes
Rhode Island	After January 1, 2024	Any, direct food contact	Legislation notes processing agent, mold release agent or intermediates are considered intentional introduction of PFAS, PFAS introduced by recycled material feedstock is not intentional	Yes
Vermont	After July 1, 2023	Any, direct food contact	Manufacturers must provide a CoC upon request	Yes
Washington	Two years after safer alternative report is submitted for a given application. First ban effective February 2023	Paper, specific identified products	Safer alternative provision	Yes



Children's and/or juvenile products

- ▶ California's bill bans both intentional PFAS as well as **unintentional** PFAS above 100 ppm.
- ▶ Washington, Vermont, Maine and Oregon mandate annual reports on PFAS usage in children's products
- ▶ Additional "High Priority Chemicals" may similarly be restricted

Drinking Water

- ▶ The US Environmental Protection Agency (EPA) has proposed a drinking water limitation for six PFAS on March 14th, 2023
- ▶ In addition, 10 states have enforceable drinking water standards already set, with 3 more state enforceable standards currently pending
 - ▶ California is the lowest at 10 ppt for PFOA and 40 ppt for PFOS



EU-PFAS tonnages in 2020 including their use in FCM*

Application	PFAAs and PFAA precursors (t/y)			Fluorinated gases (t/y)			Polymeric PFASs (t/y)			Total PFASs (t/y)		
	low	mid	high	low	mid	high	low	mid	high	low	mid	high
Manufacture	53 902	85 977	118 051	15 000	95 774	176 548	49 000	75 381	101 763	117 902	257 132	396 362
TULAC ^b	8 092	20 620	33 148				33 091	71 318	109 544	41 183	91 938	142 692
Food contact materials and packaging	3 267	6 305	9 342				15 330	17 880	20 430	18 597	24 185	29 772
Metal plating and manufacture of metal products	2	30	57				960	960	960	962	990	1 017
Consumer mixtures										21	26	30
Cosmetics										0.028	32.1	64.2
Ski wax										1.6	1.6	1.6
Applications of fluorinated gases ^{c,d}				493 173 30 671	493 173 30 671	493 173 30 671				493 173 30 671	493 173 30 671	493 173 30 671
Medical devices	1 279	2 387	3 495	20 160	33 080	46 000	3 233	7 633	12 032	24 672	43 100	61 527
Transport ^c							97 216 6 410	159 712 10 532	222 208 14 653	97 216 6 410	159 712 10 532	222 208 14 653
Electronics and semiconductors	841	1 195	1 549	140	140	140	1 560	3 088	4 615	2 541	4 423	6 304
Energy sector	293	294	294				2 592	2 756	2 920	2 885	3 050	3 214
Construction products	987	1 696	2 405				4 254	7 287	10 320	5 241	8 983	12 725
Lubricants	1	6	10	70	110	150	1 100	1 550	2 000	1 171	1 666	2 160
Petroleum and mining	4.4	7	9.5				3 500	5 500	7 500	3 504	5 507	7 510
TOTAL (excl. manufacture)^e	14 766	32 540	50 310	513 543	526 503	539 463	162 836	277 684	392 529	691 168	836 787	982 398
Total ^f	14 766	32 540	50 310	51 041	64 001	76 961	72 030	128 504	184 974	137 860	225 105	312 341

a: In some cases a basis for providing a range is lacking. There the available estimate is applied throughout; b: TULAC = Textile, upholstery, leather, apparel and carpets; c: For these sectors the tonnages relate to "technical stock volume" (presented in italics), representing an estimated 2020 PFAS volume in use in the sector as a whole. For reference only, the tonnages brought new to market in 2020 are also given; d: Includes tonnages for fluorinated gases in transport sector; e: Total based on best available data (stock if available, new to market if stock is not available); f: For reference only, also the total new manufactured tonnage put on market in 2020 is presented.

* ECHA, Annex XV Restriction Report, 22 March 2023: <https://echa.europa.eu/documents/10162/f71f3bed-e48d-5004-d195-e293c38d0602>



- ▶ **EU's Chemical Strategy for Sustainability** includes a comprehensive set of actions around PFAS with a goal to phase them out in the EU for any nonessential use
- ▶ PFAS are currently regulated under EU's Regulation on Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)
- ▶ There is a proposal issued **February 2023**, which is currently under a six-month public consultation period
- ▶ This proposal would ban the manufacture, use and placing on the market of any regulated PFAS and would be in effect 18 months from the entry into force
 - ▶ *PFAS defined as any substance that contains at least one fully fluorinated methyl (CF_3 -) or methylene ($-\text{CF}_2-$) carbon atom (without any H/Cl/Br/I attached to it)*
- ▶ PFAS are currently also restricted under EU's Persistent Organic Pollutants (POPs) regulations

To-dos on basis of current restriction proposal

Step 1: Do my products contain PFAS?

► Which PFAS definition to use ? →

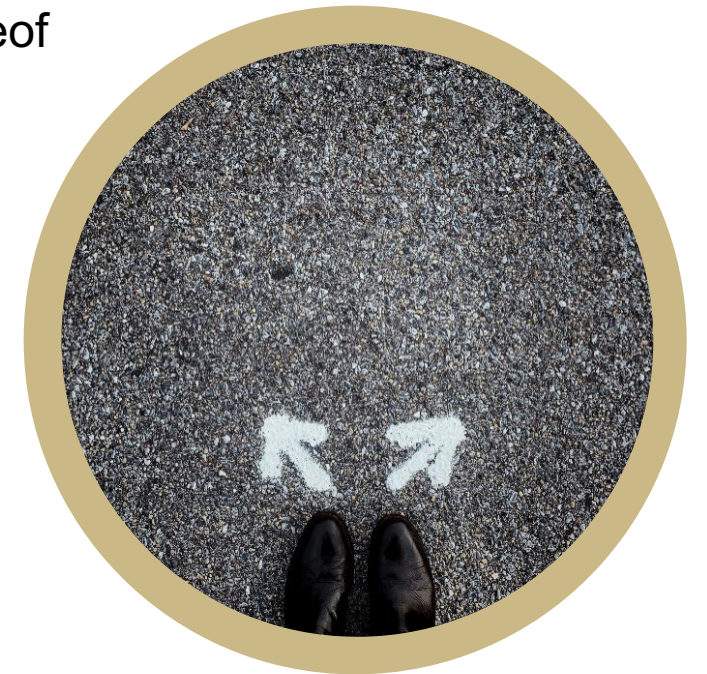
Step 2: Can PFAS be substituted at all ?

Step 3: Consider participating in public consultation



Do my products contain PFAS at all ?

- ▮ Usually no overview on substances contained in articles & parts thereof
 - ▮ Suppliers do not provide information
 - ▮ Highly complex supply chains
 - ▮ Especially for EEE: highly complex articles
- ▮ Testing may be needed



Step 2: Substitution of PFAS ?

Can PFAS be substituted at all?

- Do alternatives exist?
 - Are they feasible for my application?
 - What is needed before substitution can take place?
 - Timelines?
 - Limitations?
 - Costs?
 - Documentation!
- No alternatives available?
 - R&D activities ongoing?
 - Timelines?
 - Costs?
 - Documentation!



Step 3: Participation in public consultation

- ▶ Consider participating *via* a trade association
- ▶ Comment on the sections relevant for you
- ▶ Provide evidence!
- ▶ Information can be claimed as confidential
 - ▶ Only if strictly necessary!



Possible approaches for Product Stewardship on PFAS

- ▶ Intensify supplier communication
 - ▶ Raise awareness among suppliers
- ▶ Consider testing if no sufficient information available
- ▶ Ask suppliers for PFAS declarations
- ▶ In case of confidential information: suppliers may review with third parties under an NDA
- ▶ Be up-to-date on new regulatory measures on PFAS in relation to their use / presence in FCM/ FCA



Thank you for your time!

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